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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/786,810	02/25/2004	Jesus Benavides	ST01023 US CNT	3346

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EXAMINER	
CHONG, YONG SOO	

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 11/30/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/786,810	BENAVIDES ET AL.	
	Examiner	Art Unit	
	Yong S. Chong	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-36* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to the following inventions is required under 35 U.S.C. 121:

I. Claims 1, 2 (in part), 3 (in part), 4, 20, 21 (in part), 22 (in part), 23, 35-36 are drawn to a composition comprising levodopa and a compound of formula 1 where R comprises an aryl group containing one or more heteroatoms such as N-{1-[bis(4-chlorophenyl)methyl]azetidin-3-yl}-N-(pyrid-3-yl)methylsulfonamide, classified in 514/210.21; 514/567.

II. Claims 1, 2 (in part), 3 (in part), 5, 20, 21 (in part), 22 (in part), 24, 35-36 are drawn to a composition comprising ropinirole and a compound of formula 1 where R comprises an aryl group containing one or more heteroatoms such as N-{1-[bis(4-chlorophenyl)methyl]azetidin-3-yl}-N-(pyrid-3-yl)methylsulfonamide, classified in 514/210.21; 514/567.

III. Claims 1, 2 (in part), 3 (in part), 6, 20, 21 (in part), 22 (in part), 25, 35-36 are drawn to a composition comprising bromocriptine and a compound of formula 1 where R comprises an aryl group containing one or more heteroatoms such as N-{1-[bis(4-chlorophenyl)methyl]azetidin-3-yl}-N-(pyrid-3-yl)methylsulfonamide, classified in 514/210.21; 514/254.02.

IV. Claims 1, 2 (in part), 3 (in part), 7, 20, 21 (in part), 22 (in part), 26, 35-36 are drawn to a composition comprising pramixepole and a compound of formula 1 where R comprises an aryl group containing one or more heteroatoms such as N-{1-[bis(4-chlorophenyl)methyl]azetidin-3-yl}-N-(pyrid-3-yl)methylsulfonamide, classified in 514/210.21; 514/367.

V. Claims 1, 2 (in part), 3 (in part), 8, 20, 21 (in part), 22 (in part), 27, 35-36 are drawn to a composition comprising rasagiline and a compound of formula 1 where R comprises an aryl group containing one or more heteroatoms such as N-{1-[bis(4-chlorophenyl)methyl]azetidin-3-yl}-N-(pyrid-3-yl)methylsulfonamide, classified in 514/210.21; 514/646.

VI. Claims 1, 2 (in part), 3 (in part), 9, 20, 21 (in part), 22 (in part), 28, 35-36 are drawn to a composition comprising entacapone and a compound of formula 1 where R comprises an aryl group containing one or more heteroatoms such as N-{1-[bis(4-chlorophenyl)methyl]azetidin-3-yl}-N-(pyrid-3-yl)methylsulfonamide, classified in 514/210.21; 514/476.

VII. Claims 1, 2 (in part), 3 (in part), 10, 20, 21 (in part), 22 (in part), 29, 35-36 are drawn to a composition comprising levodopa and a compound of

formula 1 where R comprises an aryl group such as N-{1-[bis(4-chlorophenyl)methyl]azetidin-3-yl}-N-(3,5-difluorophenyl)methylsulfonamide, classified in 514/210.16; 514/567.

VIII. Claims 1, 2 (in part), 3 (in part), 11, 20, 21 (in part), 22 (in part), 30, 35-36 are drawn to a composition comprising ropinirole and a compound of formula 1 where R comprises an aryl group such as N-{1-[bis(4-chlorophenyl)methyl]azetidin-3-yl}-N-(3,5-difluorophenyl)methylsulfonamide, classified in 514/210.16; 514/567.

IX. Claims 1, 2 (in part), 3 (in part), 12, 20, 21 (in part), 22 (in part), 31, 35-36 are drawn to a composition comprising bromocriptine and a compound of formula 1 where R comprises an aryl group such as N-{1-[bis(4-chlorophenyl)methyl]azetidin-3-yl}-N-(3,5-difluorophenyl)methylsulfonamide, classified in 514/210.16; 514/254.02.

X. Claims 1, 2 (in part), 3 (in part), 13, 20, 21 (in part), 22 (in part), 32, 35-36 are drawn to a composition comprising pramixepole and a compound of formula 1 where R comprises an aryl group such as N-{1-[bis(4-chlorophenyl)methyl]azetidin-3-yl}-N-(3,5-difluorophenyl)methylsulfonamide, classified in 514/210.16; 514/367.

XI. Claims 1, 2 (in part), 3 (in part), 14, 20, 21 (in part), 22 (in part), 33, 35-36 are drawn to a composition comprising rasagiline and a compound of formula 1 where R comprises an aryl group such as N-{1-[bis(4-chlorophenyl)methyl]azetidin-3-yl}-N-(3,5-difluorophenyl)methylsulfonamide, classified in 514/210.16; 514/646.

XII. Claims 1, 2 (in part), 3 (in part), 15, 20, 21 (in part), 22 (in part), 34, 35-36 are drawn to a composition comprising entacapone and a compound of formula 1 where R comprises an aryl group such as N-{1-[bis(4-chlorophenyl)methyl]azetidin-3-yl}-N-(3,5-difluorophenyl)methylsulfonamide, classified in 514/210.16; 514/476.

XIII. Claims 1, 2 (in part), 3 (in part), 20, 21 (in part), 22 (in part), 34, 35-36 are drawn to a composition comprising a product which activates dopaminergic neurotransmission in the brain (which is not levodopa, ropinirole, bromocriptine, pramixepole, rasagiline, and entacapone), and a compound of formula 1 where R comprises an aryl group containing one or more heteroatoms such as N-{1-[bis(4-chlorophenyl)methyl]azetidin-3-yl}-N-(pyrid-3-yl)methylsulfonamide, classified in 514/210.21.

XIV. Claims 1, 2 (in part), 3 (in part), 20, 21 (in part), 22 (in part), 34, 35-36 are drawn to a composition comprising a product which activates

dopaminergic neurotransmission in the brain (which is not levodopa, ropinirole, bromocriptine, pramixepole, rasagiline, and entacapone), and a compound of formula 1 where R comprises an aryl group such as N-{1-[bis(4-chlorophenyl)methyl]azetidin-3-yl}-N-(3,5-difluorophenyl)methylsulfonamide, classified in 514/210.16.

XV. Claims 16, 17 (in part), 18 (in part), 19 are drawn to a method of treating Parkinson's disease in a patient by administering a composition comprising a product which activates dopaminergic neurotransmission in the brain and a compound of formula 1 where R comprises an aryl group containing one or more heteroatoms such as N-{1-[bis(4-chlorophenyl)methyl]azetidin-3-yl}-N-(pyrid-3-yl)methylsulfonamide, classified in 514/210.21.

XVI. Claims 16, 17 (in part), 18 (in part), 19 are drawn to a method of treating Parkinson's disease in a patient by administering a composition comprising a product which activates dopaminergic neurotransmission in the brain and a compound of formula 1 where R comprises an aryl group such as N-{1-[bis(4-chlorophenyl)methyl]azetidin-3-yl}-N-(3,5-difluorophenyl)methylsulfonamide, classified in 514/210.16.

The inventions are distinct, each from the other because of the following reasons:

Inventions I-XIV and XV-XVI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, Parkinson's disease can be treated by other methods. Regular physical exercise and/or therapy are beneficial to the patient and essential for maintaining and improving mobility, flexibility, balance and a range of motion, and for a better resistance against many of the secondary symptoms and side effects..

Inventions I-VI, XIII, XV and VII-XII, XIV, XVI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and

they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions N-{1-[bis(4-chlorophenyl)methyl]azetidin-3-yl}-N-(pyrid-3-yl)methylsulfonamide and N-{1-[bis(4-chlorophenyl)methyl]azetidin-3-yl}-N-(3,5-difluorophenyl)methylsulfonamide are totally different compounds. They have different structures, thus leading to different reactivity, binding affinity, mechanism, stability, polarity, bioavailability, efficacy, solubility, and modes of action. Furthermore, the search for N-{1-[bis(4-chlorophenyl)methyl]azetidin-3-yl}-N-(pyrid-3-yl)methylsulfonamide will not lead to information regarding N-{1-[bis(4-chlorophenyl)methyl]azetidin-3-yl}-N-(3,5-difluorophenyl)methylsulfonamide, and vice versa. Because these inventions are distinct for the reasons given above and the search required for one invention is not required for another, restriction for examination purposes as indicated is proper.

Inventions I-VI, VII-XII, and XIII-XVI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions relate to compounds which activate dopaminergic neurotransmission in the brain and are totally different compounds. They have different structures, thus leading to different reactivity, binding affinity, mechanism, stability, polarity, bioavailability, efficacy, solubility, and modes of action. Furthermore, the search for one will not lead to information regarding the other, and vice versa. Because these inventions are distinct for the reasons given above and

the search required for one invention is not required for another, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement is traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

A telephone call to the attorney is not required where: 1) the restriction requirement is complex, 2) the application is being prosecuted pro se, or 3) the examiner knows from past experience that a telephone election will not be made (MPEP § 812.01). Therefore, since this restriction requirement is considered complex, a call to the attorney for telephone election was not made.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong S. Chong whose telephone number is (571)-272-8513. The examiner can normally be reached on M-F, 9-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, SREENI PADMANABHAN can be reached on (571)-272-0629. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

YSC